Appendix E

BCC PROJECT STATUS REPORT SUMMARY — December, 2001

Site Name [Principal Investigator(s)]	Project Name	Project Manager(s)	Sample Size	% Recruited	Baseline Data Completion	Intervention Length	Follow-Up Schedule
Brown University/ The Miriam Hospital [Belinda Borrelli]	PAQS Project	Deborah Sepinwall	288	30	Nov., 2003	2 months	12 months
Cornell University [Mary Charlson]	Health Behaviors	Lynn Burrell	660	100	Done	2 years	Every 3 months

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Site Name (cont'd/…)	Recruitment & Retention Challenges/Solutions	Treatment/Intervention Delivery Challenges/Solutions	Data Collection/Analysis Challenges/Solutions
Brown University/ The Miriam Hospital	• Staff shortage at referral agency. Trained RA to screen individuals for eligibility; regular contact meetings with referral agency to address recruitment issues; establishing study presence at referral agency. • Unable to recruit Spanish participants due to language barrier . Hired Spanish-speaking nurse and RA; translated all study materials to Spanish. • Attracting subjects to and retaining them in study. Enhanced incentive package; identified other recruitment channels.	• Nurse attrition; visits not occurring in timely fashion. Hired nurse manager to ease individual nurse burden; hired new nurses; frequent quality control check with nurses; nurse completes checklist to ascertain performance of assigned tasks; taping treatment sessions; providing feedback to nurses.	• Difficulty reaching participants. Attempt at different times of day and night. • Patient no shows. Call to confirm the appt. on the day of the appt. • Distractions during the in-home interview (e.g., children, phone, visitors). Ask if there is a quiet place to meet and complete questionnaires. Indicate to participant in advance the length of the questionnaire so that they can plan for childcare, etc., accordingly. • Difficulty comprehending questions. Encourage participant to ask questions. Confirm apparent discrepancies in responses.
Cornell University	• Retention of patients at each follow-up. To help solve this problem we have shortened our battery.	• Our biggest challenge has been standardizing the delivery of Motivational Interviewing. We have had a complete change over in staff, and have trained the new research assistants MI techniques.	None

Site Name (cont'd/…)	Preliminary Findings	Publications To-Date	Cross-Site Discussion Topics
Brown University/ The Miriam Hospital	None	None	
Cornell University	**Baseline Demographics** • Age: mean (±SD) 63.2 yrs. (± 11.6; range 33-93) • Sex: 27.1% female • Race: African American 11.7% Asian/Pacific Islander 4.7% Hispanic 9.1% Caucasian 74.5% • Depression: 30.6%		

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Site Name [Principal Investigator(s)]	Project Name	Project Manager(s)	Sample Size	% Recruited	Baseline Data Completion	Intervention Length	Follow-Up Schedule
Emory University [Ken Resnicow]	Healthy Body, Healthy Spirit	Dhana Blissett/Alice Jackson	1,000	100	Done	12 months	24 months
Harvard School of Public Health [Karen Peterson]	Reducing Disease Risk among Low-income, Postpartum Women	Judy Salkeld	700	15	August, 2002	12 months	18 months

Site Name (cont'd/…)	Recruitment & Retention Challenges/Solutions	Treatment/Intervention Delivery Challenges/Solutions	Data Collection/Analysis Challenges/Solutions
Emory University	• Non-working phone numbers. Have church liaison follow-up in person.	• Non working numbers for telephone counseling Have church liaison follow-up in person.	None
Harvard School of Public Health	• Connecting with eligible women at WIC clinics. Solved by enlisting support of WIC staff to recruit women. The staff keeps a stack of oversized fake $10 bills on their desks; the reverse side has a consent form to provide the participant's name and phone number so that a project person may contact them. We provide incentives for sites/staff who get the most referral slips. • Survey takes approx. one hour to complete. Women recruited at a WIC clinic typically don't have this amount of time. Make an appointment to go to woman's home to complete survey.	• Cancellations and no-shows for home visits are the major challenge. No real solution, just persistence and frequent reminders ultimately result in success. • Promoting attendance at group sessions. We hope to solve this by promoting a party atmosphere and providing transportation and child care	N/A

Site Name (cont'd/…)	Preliminary Findings	Publications To-Date	Cross-Site Discussion Topics
Emory University	• Praise dancing accounted for approximately 13% of weekly METS in our sample! • Champs self-reported activity questionnaire correlated around .28 with submax treadmill	• Resnicow K, DiIorio C, Soet J, Borrelli B, Ernst D, Hecht J. (2001). Motivational Interviewing in Health Promotion: It sounds like something is changing. Manuscript submitted for publication. • Resnicow K, DiIorio C, Soet J, Borrelli B, Ernst D, Hecht J, Thevos A. (in press). Interviewing in medical and public health settings. In W. Miller, & S. Rollnick (Eds.), Motivational Interviewing (2nd ed.). New York: Guildford Publications Inc. • Resnicow K, McCarty, F, Blisset, D, Jackson, A, Wang, T, & Baranowski, T. (2001). Praise Dancing as a source of physical activity among African American adults. Manuscript submitted for publication.	• Cross-site analyses continuation funding.
Harvard School of Public Health	None	None	• Findings regarding environmental determinants of physical activity.

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Site Name [Principal Investigator(s)]	Project Name	Project Manager(s)	Sample Size	% Recruited	Baseline Data Completion	Intervention Length	Follow-Up Schedule
Illinois Institute of Technology [Tamara Goldman-Sher]	A Couples Intervention for Cardiac Risk Reduction	Jennifer Tennant	160	21	August, 2002	6 months	9, 12 & 18 months

Site Name (cont'd/…)	Recruitment & Retention Challenges/Solutions	Treatment/Intervention Delivery Challenges/Solutions	Data Collection/Analysis Challenges/Solutions
Illinois Institute of Technology	• Our third site has taken a very long time to get up and running. • One of the biggest problems at the county hospital is contacting potential participants after they leave the clinic. They often don't have voice mail or answering machines. Many of them don't have phones at all and give you numbers of relatives or neighbors so it is difficult to reach them. • Our main hospital site provides care to patients from the entire Chicago area, many of whom are willing to drive a long distance for an office visit or procedure but not on a weekly visit for our study intervention. • Recruitment of women is lower than anticipated. Younger women often have multiple roles and can't find the time and older women are more often without a spouse and have other co-morbid diseases that exclude them from participation. • Overall retention is good. Participants who have dropped out have done so prior to the intervention (due to time, family commitments, new health problems, moving farther away or being randomized to a group other than the one they wanted).	• We have experienced no challenges to the delivery of our treatment. The sessions are delivered as planned and are according to the manual. Our recruitment is behind schedule but has increased substantially over the last 6 months.	• We are currently exploring various ways to manage our very large data set. The particular issues facing us include missing data and the appropriate change analyses for non-independent (husbands and wives) data.

Site Name (cont'd/…)	Preliminary Findings	Publications To-Date	Cross-Site Discussion Topics
Illinois Institute of Technology	• Our pilot data informed us that our treatment was well tolerated, that the group format was acceptable to participants, and that it is possible for us to track patients over time.	• We just finished a chapter on Couples and Illness.	• We are very interested in seeing more data management/analyses discussions.

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Site Name [Principal Investigator(s)]	Project Name	Project Manager(s)	Sample Size	% Recruited	Baseline Data Completion	Intervention Length	Follow-Up Schedule
Kansas State University [David Dzewaltowski]	Healthy Youth Places Project	Jennie Hill	16 (schools)	100	Done	2 years	1, 2, & 3 years (Grades 7, 8, 9)
Stanford University [Abby King]	CHAT	Cynthia Castro	225	60	2002	18 months	3, 6, 12, & 18 months

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Site Name (cont'd/…)	Recruitment & Retention Challenges/Solutions	Treatment/Intervention Delivery Challenges/Solutions	Data Collection/Analysis Challenges/Solutions
Kansas State University	• Children leaving intervention and control schools in ethnically diverse and low SES neighborhoods is likely to be greater than expected over the length of the four-year study. • Transfer from inner city schools may be larger than expected. • To help account for student transfer, we have obtained district wide identifiers and can track students across schools and within districts.	• We are studying the process of delivery in schools. It is a major problem and major aim of the grant. • We are solving these problems by applying theory at the process level and studying the process of implementation	• No unexpected challenges
Stanford University	None	None	None

Site Name (cont'd/…)	Preliminary Findings	Publications To-Date	Cross-Site Discussion Topics
Kansas State University	• Psychometric analyses show that our measures at baseline are acceptable. • School level SES relationship with physical activity is mediated by self-efficacy: A multilevel analysis. The purpose of this study was to examine if school level socioeconomic status (environment) related to physical activity and if this relationship was mediated by individual level self-efficacy of 6th grade youth. • School environment (i.e., school SES) significantly predicted MVPA (Beta =-2.51; SE =.004; p < .05). In turn, school SES significantly predicted the hypothesized mediators of PASE (b=-.009; SE = .002; Beta =-5.92) and parent ECSE (b = -.011, SE = .002, Beta = -6.83, p < .05), but did not relate to school ECSE. • Further, PASE (b=.309; SE = .046; Beta = 6.76; p < .05) and parent ECSE were significant predictors of MVPA and school SES was no longer a significant predictor. • The test for mediation of school SES on MVPA by PASE was significant (z=-4.736, p < .05). Thus, the poorer the school, the lower students' self-efficacy to be physically active, the lower students' self-efficacy to get their parents to change their after school physical activity environment, and the lower their MVPA.	• Dietary Supplement Use Among Sixth Grade Students (Manuscript Submitted) • Development of The After School-Program Group Environment Questionnaire: A Cohesion Inventory for Middle Schools (Manuscript Submitted) • Dzewaltowski, D.A., Estabrooks, P.A., Johnston. J.A., & Gyurcsik, N.C. (in press). Promoting physical activity through community development. In J. L. Van Raalte, & B. W. Brewer (Eds.), Exploring Sport & Exercise Psychology (2nd ed.). American Psychological Association: Washington, D.C. • Ryan, G.J., & Dzewaltowski D.A. (in press). Self-efficacy as a determinant of after-school physical activity among sixth- and seventh-grade students. Health Education and Behavior. • Estabrooks P.A., Dzewaltowski, D.A., Karteroliotis, K., Gyurcsik, N.C., Hill, J..L., & Ryan, G.J. (Submitted). Development of The After School-Program Group Environment Questionnaire: A cohesion inventory for middle schools. • Hill J.L., Dzewaltowski D.A., & Estabrooks P.A. (Submitted). Dietary supplement use among sixth grade students.	• Physical activity and fruit and vegetable environmental change self-efficacy: Theory and measurement
Stanford University	None	None	None

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Site Name [Principal Investigator(s)]	Project Name	Project Manager(s)	Sample Size	% Recruited	Baseline Data Completion	Intervention Length	Follow-Up Schedule
Oregon Health Sciences University [Diane Elliot]	PHLAME Study	Rosemary Johnson	608	100	Done	24 months	12 & 24 months
Oregon Research Institute [Deborah Toobert]	Enhancing Support for Health Behavior Change Among Women at Risk for Heart Disease (CHDRISK)	Lisa Strycker	250	100	Done	6 months	6, 12 & 24 months

Site Name (cont'd/…)	Recruitment & Retention Challenges/Solutions	Treatment/Intervention Delivery Challenges/Solutions	Data Collection/Analysis Challenges/Solutions
Oregon Health Sciences University	• Firefighters choosing not to come in for follow-up assessments and/or to drop out of study. (One common misconception is that fire fighters feel they need to make changes to be in the study or be retested.) We have developed a protocol that includes a script of importance around continued participation and follow-up assessments and if needed a follow-up phone call by a co-investigator. We also visit fire stations before scheduled follow-up assessments to encourage continued participation.	• Scheduling team intervention sessions has been challenging because of the firefighters' work schedules. Most team members need to be on duty to hold a session. To deal with this, we have assigned stations liaisons that make reminder and follow-up phone calls and reschedule if necessary.	• At baseline assessment questionnaire completion was time consuming for firefighters testing at OHSU. On follow-up assessments, questionnaires are administered at the station. Testing has been structured more efficiently.
Oregon Research Institute	• We have had 45 drop-outs (16%) of our sample. Consulted with an MI expert; designed contests, including attendance rewards; and dismantled as many barriers to attendance as possible.	• Re-randomization to one of two maintenance conditions. Some of those randomized to the personalized support condition were emotionally upset and having to stop coming to the weekly meetings..	• Completion of all the assessment pieces at all assessment points. Some participants don't return 2-week diaries, and 7-day monitoring forms. We try asking them to do 4 days (on the 7-day form) and that has helped some. Other participants have not been able to do any days. A few people have not returned for the 2nd part of their 6-month assessment visit. • It is difficult to decide who is a dropout. Some of the women have dropped the weekly meetings but are willing to come to the assessments. • Complaints about the length of assessments by study participants. • People physically unable to do some of the physical assessments (sit-and-reach). • Problems with: a) equipment (misuse of the pedometers, lost pedometers, or pedometers not working); b) compliance on the 7-day self-monitoring form; c) missing responses in a large survey battery.

Site Name (cont'd/…)	Preliminary Findings	Publications To-Date	Cross-Site Discussion Topics
Oregon Health Sciences University	• Pilot study results showed significant improvements in station exercise and eating habits and group cohesion for team intervention participants. • There were significant decreases in depressive symptoms and increases in personal exercise habits for participants in the one-on-one intervention. • Both groups had significant decreases in LDL cholesterol.		
Oregon Research Institute	We have significant six-month improvements for the treatment group on: • diet (NCI F&V Screener, NCI Fat Screener, Kristal FHQ, and a global self-report measure); • anthropomorphic improvements (weight loss, BMI, and waist/hip ratio); • exercise (CHAMPS; self-monitored minutes or Pedometer not yet analyzed); • stress-management practice (global self-report, self-monitored minutes, but not on range-of-motion or sit and reach); • blood pressure (systolic and diastolic, staff measured); • perceived social support (UCLA, Cohen social network, Chronic Illness Resources Survey); and • hemoglobin (A1c, but not on lipids).	• Toobert, D.J., Strycker, L.A., Glasgow, R. E., & Bagdade, J. D. (2001). If you build it, will they come? Reach and adoption associated with a comprehensive lifestyle management program for women with type 2 diabetes. Manuscript submitted to Patient Education and Counseling.	

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Site Name [Principal Investigator(s)]	Project Name	Project Manager(s)	Sample Size	% Recruited	Baseline Data Completion	Intervention Length	Follow-Up Schedule
University of Maryland [Barbara Resnick]	Testing the Effectiveness of the Exercise Plus Program	Veritas Custis Buie	240	25	Sept., 2002	12 months	2, 6 & 12 months
University of Michigan/ Henry Ford Health Center [Vic Strecher]	Tailored Intervention for Multiple Risk Behaviors	Holly Derry (UM); Lucy Robinson (HFHS)	3,000	10	April, 2002	4 months	3 & 12 mos.
University of Minnesota [Bob Jeffery; Alex Rothman]	Challenge Study	Emily Finch	600	100	Done	8 weeks	18 months

Site Name (cont'd/…)	Recruitment & Retention Challenges/Solutions	Treatment/Intervention Delivery Challenges/Solutions	Data Collection/Analysis Challenges/Solutions
University of Maryland	• Our biggest challenge with regard to recruitment has been in numbers of eligible participants per facility. Only about 20% of those who fracture their hips are eligible. Of these, we obtain about 70-80% consent rates. • Retention is excellent — close to 100% — as we do follow up in the home setting; and retention is no a problem. • We keep expanding to new sites. We pulled out of one hospital where there were no eligible participants over 6 months and are now in 5 facilities and going into two more. • The main challenge is getting through all these IRB's; it is a 6-month process.	• Biggest challenges are: (1) staff retention of trainers, in particular. We have had several with us for years but a few have been short turnarounds and this is difficult as the study requires significant amounts of training; and (2) barriers to exercise by orthopedists and family who feel the older women is 'too frail,' 'won't benefit,' that type of thing. • With the significant IRB concerns currently we must proceed very cautiously in any of our questionable situations and thus can't push too hard.	• Getting to the participant in a timely fashion has been our biggest challenge as the baseline is a time when these individuals are pretty immediate post-op and fatigued and don't want to always answer all the questions. In addition, they may be moving from one site to another — rehab to home, or hospital to rehab.
University of Michigan/ Henry Ford Health Center	• Recruitment is incredibly slow. We're hiring as many interviewers as we can, but it's difficult to get a hold of people. The biggest challenge is reaching people, followed by people being ineligible (when in fact they should be eligible). We're trying new strategies to deal with the eligibility issues, but reaching people is still an issue.	None	• Our computer-assisted interviewing system is sometimes slow, but the technology support people are constantly working on ways to improve it.
University of Minnesota	• We have used television advertising with good success for recruitment. • Retention rates have been somewhat lower than expected. We have tried to solve this by mailing and phoning participants with reminders.	None	None

Site Name (cont'd/…)	Preliminary Findings	Publications To-Date	Cross-Site Discussion Topics
University of Maryland	• Barb Resnick has done some qualitative work on another one of the hip studies to see how participants felt about the Exercise Plus Program (the total program). A total of 20 women participated thus far. Resnick did pilot work on the social support for exercise measure being used in the study, and pilot work on the SAM both of which have been accepted for publication and are coming out in the next month or so. Resnick would be happy to share abstracts of results on all of these if anyone is interested.	• Resnick et al. (in press). The impact of social support on exercise. Clinical Nursing Research. • Resnick et al. (2001). Testing the reliability and validity of the Step Activity Monitor. Journal of Nursing Measurement, 9(3), 12-16.	• Continued discussion about cross-site studies. • Continued discussion about data analysis of cross study. • Continued discussion about cost analysis of both intervention and cost of study implementation with regard to recruitment and retention
University of Michigan/ Henry Ford Health Center	None	None	None
University of Minnesota	[2] Please see Footnote		

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Site Name [Principal Investigator(s)]	Project Name	Project Manager(s)	Sample Size	% Recruited	Baseline Data Completion	Intervention Length	Follow-Up Schedule
University of Rhode Island [Phil Clark]	The SENIOR Project (Study of Exercise and Nutrition in Older Rhode Islanders)	Faith Lees; Sandra Saunders	1,270	100	Done	12 months	12 & 24 months
University of Rochester [Geof Williams]	Smokers' Health Study	Chantal Levesque	1,000	76	March, 2002	6 months	1, 6 & 18 months
University of Tennessee [Robert Garrison]	HOPE (Health Opportunities With Physical Exercise)	Mace Coday	360	100	Done	24 months	6, 12 & 24 months

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Site Name (cont'd/…)	Recruitment & Retention Challenges/Solutions	Treatment/Intervention Delivery Challenges/Solutions	Data Collection/Analysis Challenges/Solutions
University of Rhode Island	• Challenge in recruiting last 300 of total sample of 1,300 Expanded recruitment area to neighboring communities, and unofficially dropped age eligibility to 60.	• Telephone intervention challenges: 1) staff (i.e. counselor) turnover; 2) maintaining tracking system and 3) some language barrier challenges 1) trained new staff; 2) hired new staff; and 3) recruited bi-lingual staff.	None
University of Rochester	• Keeping people at the follow-ups. • Finding resources to increase number of contacts to 15. • Trying to reduce the number of people who drop. The majority of our drops are coming from the smoking intervention/diet intervention condition. • We advertise regularly and in high circulation newspapers. We also put flyers into physicians' and dentists' offices.	• Trying to make the intervention and the dose similar across counselors. We resolved this issue by having regular supervision sessions.	None
University of Tennessee	• Retention rates are running 88% at 6 months. Rescheduling appointments is often as necessary helps, and using gift certificates to shopping mall as incentives for out of window participants with some success. Triaging calls among staff and having CO-I make calls too helps with some more resistant participants.	• Challenge has been delivery of the peer intervention. Consistent paper documentation of peer-participant contacts has been a problem. Having provider interventionists perform random QC checks and regular group and individual booster trainings for peers helping	None

Site Name (cont'd/…)	Preliminary Findings	Publications To-Date	Cross-Site Discussion Topics
University of Rhode Island	Baseline data analyses are currently underway		
University of Rochester	None	N/A	• How many times should we try to contact people before we stop calling?
University of Tennessee	None	N/A	• Planning and submitting competitive renewals • Manuscripts submitted, overview and suggestions for similar work.

Appendix E

[1] Cornell Preliminary Findings		
Baseline Clinical Characteristics		**Clinical Features Post-Procedure**
• Clinical features pre-procedure:	• Vessel Diseased (% occlusion):	• Medications:
History of Hypertension 56.7%	Left Main:	Anti-coagulants 99.0%
Prior Myocardial Infraction 37.4%	50-69% 2.9%	Beta Blockers 60.2%
Prior Angioplasty/Stent 21.6%	70-89% 1.0%	Nitrates 28.6%
Prior Bypass Surgery 7.3%	90-100% 0.7%	ACE Inhibitors 20.4%
• Stress Test results:	Proximal Left Anterior Descending:	Ca Channel Blockers 10.0%
Postitive 57.4%	50-69% 2.4%	Diuretics 11.6%
Negative 1.0%	70-100% 32.3%	Anti-arrhythmic 0.5%
• Canadian Cardiovascular angina class:	Mid/Distal Left Anterior Descending:	
No Angina 46.1%	50-69% 6.8%	
Class I 6.7%	70-100% 49.5%	
Class II 6.5%	Right Coronary/Posterior Descending:	
Class III 3.8%	50-69% 5.1%	
Class IV 37.3%	70-100% 51.5%	
• Angina Type:	Left Circumflex or Large Marginal:	
Stable 49.7%	50-69% 4.9%	
Unstable 37.3%	70-100% 43.9%	
• Ejection Fraction:	• Number of vessels receiving Angioplasty/ Stent:	
(mean ± SD) 50.4% ± 10.7%	1 65.4%	
	2 26.3%	
	3 6.5%	
	4 1.8%	

[2] The study was designed to examine the effect that people's expectations about behavior change have on short- and long-term behavioral outcomes. Participants were randomly assigned to one of two treatment conditions that were designed to modify people's expectations about the process and outcomes associated with smoking cessation. Participants in the optimistic condition were taught to systematically focus on the benefits of quitting, whereas those in the balanced condition were taught to systematically focus on both the benefits and costs of quitting. We hypothesized that smokers in the optimistic condition would be more likely to make a quit attempt and more likely to persist in their initial efforts to quit smoking than would smokers in the balanced condition. We did find that participants in the optimistic condition were slightly more likely to quit smoking than participants in the balanced condition as measured 4 weeks after the quit date. However, this result was not statistically significant. We have found that the effect of the optimistic condition was contingent on having had some prior success with cessation. The sample was split into two groups: a) participants who had been quit no longer than 2 months prior to starting this study; and b) participants who had been quit for 3 months or longer at some point prior to starting the study. These two groups do not differ on a) gender, b) education level, c) years' smoking, d) prior quit efforts. We found that the optimistic treatment was more effective at helping people quit who had a prior long quit, whereas the balanced treatment was more effective at helping people quit for those participants with short prior quits.